REMARKS

This Amendment is responsive to the Final Office Action dated August 6, 2009. By this Amendment, Applicant has amended claims 1 and 3-6. Also, by this Amendment, Applicant has cancelled claims 7-41 and added new claims 42-59. Claims 1-6 and 42-59 are pending.

Claim Rejection Under 35 U.S.C. § 102

In the Final Office Action, the Examiner rejected claims 1, 2 and 6 under 35 U.S.C. § 102(e) as being anticipated by Steil et al. (U.S. Patent Publication No. 2003/0130616, hereinafter "Steil"); and rejected claims 3-6 under 35 U.S.C. § 102(b) as being anticipated by Ellinwood, Jr. (U.S. Patent No. 4,146,029, "hereinafter Ellinwood").

Applicant respectfully traverses the rejections to the extent the rejections may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102, and provide no teaching that would have suggested desirability of modification to include such features.

Applicant respectfully submits that neither Steil nor Ellinwood, alone or in combination, discloses each and every feature of Applicant's independent claims 1, 3, and 6. The references cited in the Office Action further provide no teaching that would have suggested a rational reason to include such features.

Steil

Applicant respectfully traverses the rejection of claims 1, 2 and 6 as anticipated by Steil, because Steil fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested a rational reason to include such features.

For example, Steil does not disclose "an interactive remote drug dose and physiologic response monitoring system comprising a drug delivery device; and an IMD in wireless communication with the drug delivery device, the IMD having means for monitoring the administration of a drug by the drug delivery device in compliance with a prescriptive regimen, wherein the IMD monitors the patient's physiological signs subsequent to the administration of the drug," as recited in Applicant's amended claim 1.

As another example, Steil does not disclose "an implantable medical device comprising a controller for controlling cardiac therapy parameters, one or more electrodes for delivering

electrical stimulation to cardiac tissue and monitoring physiologic parameters of the tissue, wherein the controller receives the parameters from the electrodes and information from a drug delivery device, the information identifying whether an expected drug therapy is delivered, and wherein the controller varies the cardiac therapy delivery through the electrode based upon the parameters and the information," as recited in Applicant's amended claim 6.

Steil is generally directed to a closed-loop insulin delivery system in which one or more sensors monitor glucose concentration in the body of a user and send signals indicating glucose levels to an insulin delivery device. (Steil Abstract).

With regard to claims 1 and 6, the Final Office Action stated that Steil discloses the above-identified claim elements at paragraphs [0005], [0006], [0098], [0293] and [0317]. However, these portions of Steil do not describe any IMD having means for monitoring the administration of a drug by the drug delivery device or any other device whatsoever. Steil further does not describe any drug delivery monitoring system comprising means for monitoring parameters of a drug delivery device and means for communicating the monitored parameters with an implantable medical device (IMD).

On the contrary, paragraphs [0005], [0006] merely describe sensors that monitor glucose concentration in the body of a user and send signals indicating glucose levels to an insulin delivery device. "The sensor system includes a sensor for *monitoring a condition of the user*. The sensor *produces a sensor signal*, which *is representative of the condition of the user*, and is used to generate a controller input" (emphasis added). (Steil paragraph [0006]). As another example, paragraph [0098] of Steil describes implementation of the above-described system in a hospital environment. The glucose sensors may be "inserted through the IV line to give real-time glucose levels from the blood stream." (Steil at paragraph [0098]). As another example, paragraph [0293] of Steil discloses a list of patient body characteristics that may be measured by sensors. Steil makes no mention, however, of monitoring of administration of a drug by a drug delivery device, as set forth in claim 1, or receiving any information from a drug delivery device identifying whether an expected drug therapy is delivered, as set forth in claim 6. As yet another example, paragraph [0317] incorporates various references as examples of glucose sensor sets that measure glucose concentration in the body of a user. The sensors sets may include sensors that communicate signals indicating glucose concentration in a patient's body.

As indicated by the above-described sections of Steil, and contrary to the Examiner's assertion, Steil only discloses glucose sensors capable of monitoring body conditions of a patient, and provides no teaching that would have suggested monitoring administration of a drug by a drug delivery device, as set forth in claim 1, or receiving information from a drug delivery device identifying whether an expected drug therapy is delivered, as set forth in claim 6. The Steil glucose sensors only provide one-way communication to a drug delivery device regarding measurement of patient body characteristics.

Because the Steil glucose sensors do not receive or acquire any information from a drug delivery device, or any device, one cannot consider the Steil glucose sensors to be "an IMD having means for monitoring the administration of a drug by a drug delivery device in compliance with a prescriptive regimen," as recited in Applicant's claim 1. Because the glucose sensors are limited to one-way communication, one could not consider the sensors to include a controller that "receives... information from a drug delivery device," as recited in Applicant's amended claim 6.

Applicant respectfully submits that Steil fails to disclose each and every element set forth in independent claims 1, 2, and 6. Steil further provides no teaching that would have suggested the desirability of modification to include these claim elements. For at least those reasons discussed above, the Office Action has failed to establish a prima facie case for anticipation of Applicant's independent claims 1, and 6, under 35 U.S.C. § 102(b). Reconsideration and withdrawal of the rejection of the claims is respectfully requested.

Ellinwood

Applicant respectfully traverses the rejection of claims 3-6 as anticipated by Ellinwood, because Ellinwood fails to disclose each and every feature of claims 3-6, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested desirability of modification to include such features.

For example, Ellinwood fails to teach or suggest "A drug delivery monitoring system comprising means for monitoring parameters of a drug delivery device, means for communicating the monitored parameters with an implantable medical device (IMD), means for processing the monitored parameters; and means for controlling the drug delivery device based on the processing of the monitored parameters," as recited by Applicant's claim 3 as amended.

As another example, Ellinwood does not disclose "an implantable medical device comprising a controller for controlling cardiac therapy parameters, one or more electrodes for delivering electrical stimulation to cardiac tissue and monitoring physiologic parameters of the tissue, wherein the controller receives the parameters from the electrodes and information from a drug delivery device, the information identifying whether an expected drug therapy is delivered, and wherein the controller varies the cardiac therapy delivery through the electrode based upon the parameters and the information," as recited in Applicant's amended claim 6.

The Office Action stated that Ellinwood discloses elements of claims 3 and 6 in Figure 28, column 3, lines 9-67, column 4 lines 1-10, and column 8 lines 40-57. However, these portions of Ellinwood describe "storage, control and dispensing components of a *unitary device* being entirely implanted in the body but with selected control components being adapted to extracorporeal operator control. There is provided either one or a plurality of sensors, each of which is adapted to sense a particular *body condition* at a particular point in the body" (emphasis added). (Ellinwood at column 3, lines 9-16).

Contrary to the assertion provided in the Office Action, Ellinwood makes no mention of means for monitoring parameters of a drug delivery device and means for communicating the monitored parameters with an IMD, as recited in Applicant's claim 3 as amended. Ellinwood does not disclose any implantable device other than the drug delivery device itself that is capable of receiving or acquiring any information from another device, which would be necessary to monitor parameters of a drug delivery device and communicate monitored parameters to an IMD as claimed. Instead, Ellinwood only discloses sensors that may send information one-way to a drug delivery device. Furthermore, the Ellinwood sensors do not disclose monitoring of anything beyond patient body conditions. Thus, Ellinwood does not disclose means for monitoring parameters of a drug delivery device and means for communicating the monitored parameters with an IMD as recited in Applicant's claim 3 as amended. Further, since Ellinwood does not disclose means for monitoring parameters of a drug delivery device whatsoever, Ellinwood further does not disclose means for processing such monitored parameters and means for controlling the drug delivery device based on the processed parameters as recited in Applicant's claim 3 as amended.

Likewise, Ellinwood does not disclose "an implantable medical device, comprising: a controller for controlling cardiac therapy parameters...wherein the controller receives...

information from a drug delivery device, the information identifying whether an expected drug therapy is delivered," as included in Applicant's currently amended claim 6. Rather, Ellinwood only discloses sensors that may send information one-way to a drug delivery device. Thus, Ellinwood does not disclose an implantable medical device that includes a controller that receives information from a drug delivery device as claimed. Further, because the Ellinwood sensors only measure patient body characteristics, Ellinwood makes no mention of receiving any information that identifies whether an expected drug therapy is delivered as claimed.

Claim 6 as currently amended also recites "wherein the controller varies the cardiac therapy delivery through the one or more electrodes based upon the parameters and the information." The Office Action stated that Ellinwood discloses these claim features at Figure 28, column 3 lines 9-67, column 4 lines 1-10, and column 8 lines 40-57. However, these portions of Ellinwood describe a drug delivery device that may share a housing with a pacemaker, and corresponding control of the drug delivery device. Ellinwood states: "the sensor 30 of FIG. 1 senses the particular condition at timed intervals and the dispenser control 31 of FIG. 1 causes the dispenser mechanism, such as illustrated in my prior patent, to either operate or not operate according to the evaluation and decision based on the sensed data." (Ellinwood at column 8, lines 47-53). Administration of drug therapy by the Ellinwood device may depend on one or more sensed hemodynamic characteristics, such as a QRS complex of an EKG. (Ellinwood column 12, lines 23-45). However, contrary to the assertion made in the Office Action, Ellinwood is silent on the converse, administration of cardiac therapy delivery through one or more electrodes based upon information received from a drug delivery device.

Thus, contrary to the assertion made in the Office Action, Ellinwood makes no mention of variation of "cardiac therapy delivery through one or more electrodes based upon the parameters and the information" as recited in Applicant's claim 6 as amended, and instead refers to administration of drug therapy that may depend on one or more sensed hemodynamic characteristics, such as a QRS complex of an EKG.

Ellinwood fails to disclose each and every limitation set forth in claims 3 and 6. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 3-6 under 35 U.S.C. § 102(b). Reconsideration and withdrawal of the rejection of claims 1-6 is respectfully requested.

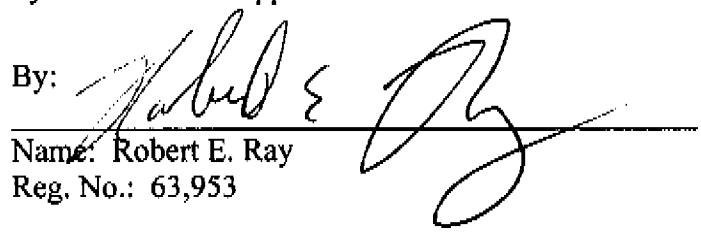
New Claims

Applicant has submitted new claims 42-48, which are dependent on claim 1. Applicant has also submitted new claims 49-55, which are dependent on claim 3. Applicant has further submitted new claims 56-59, which are dependent on claim 6. New claims 42-59 are fully supported by the disclosure as originally filed, and introduce no new matter.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: November 5, 2009

By: 

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